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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Zehra Kaymakcalan, *et al.*

Serial No.: 10/693,233

Filed: October 24, 2003

For: *LOW DOSE METHODS FOR TREATING
DISORDERS IN WHICH TNFA ACTIVITY IS
DETRIMENTAL*

Attorney Docket No.: BBI-190

Group Art Unit: 1644

Examiner: A.R. Chaudhuri

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

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Jan. 14, 2005
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By:

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INFORMATION DISCLOSURE STATEMENT

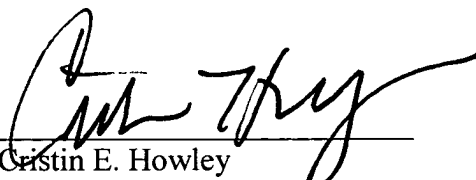
Dear Sir:

Applicant and their Agent are aware of the following publications and information, listed on the attached PTO Form SB/08, and in accordance with 37 CFR §1.97 hereby submit these publications for the Examiner's consideration. Copies of cited U.S. patents and U.S. publications (Reference ID Nos. A1-A7, B1-B13) are not enclosed with this statement. Copies of foreign patent documents and non-patent literature (Reference ID Nos. A8-A18, B14-D4) are enclosed in accordance with 37 CFR 1.98(a)(2).

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, Applicants understand that the Examiner will make an independent evaluation of the cited publications.

Under 37 CFR § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 CFR §1.17(p) to our Deposit Order Account No. 12-0080.

Respectfully submitted,
LAHIVE & COCKFIELD, LLP


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Date: January 14, 2005

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Enclosures



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* Admitted in TX only
** Admitted in CT only

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MS Amendment
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Re: U.S. Patent Application No.: 10/693,233
For: *LOW DOSE METHODS FOR TREATING DISORDERS IN WHICH TNFA
ACTIVITY IS DETRIMENTAL*
Inventors: Zehra Kaymakcalan, *et al.*
Filed: October 24, 2003
Our Ref. No.: BBI-190

Dear Sir:

I enclose herewith for filing in the above-identified application the following:

1. Information Disclosure Statement;
2. PTO Form SB/08;
3. Copies of references cited in PTO Form SB/08 (49);
4. A Return Postcard.

No additional costs are believed to be due in connection with the filing of this Information Disclosure Statement. However, please charge any necessary fees in connection with the enclosed statement to our Deposit Order Account No. 12-0080. For this purpose, a duplicate of this sheet is attached.

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MS Amendment, Commissioner for Patents, P.O. Box 1450,
Alexandria, Virginia 22313-1450 on:
Jan. 14, 2005
Date
Cristin E. Howley
Cristin E. Howley Registration No. 55,281

Respectfully submitted,
LAHIVE & COCKFIELD, LLP

Cristin E. Howley
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Agent for Applicants



PTO/SB/08a/b (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

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<p>Substitute for form 1449A/B/PTO</p> <h2 style="text-align: center;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center;">(Use as many sheets as necessary)</p>				Complete if Known	
				Application Number	10/693,233
				Filing Date	October 24, 2003
				First Named Inventor	Zehra Kaymakcalan
				Art Unit	1644
				Examiner Name	A.R. Chaudhuri
Sheet	1	of	4	Attorney Docket Number	BBI-190

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	5,231,024	07-27-1993	Moeller <i>et al.</i>	
	A2	5,698,195	12-16-1997	Le <i>et al.</i>	
	A3	5,795,967	08-18-1998	Aggarwal <i>et al.</i>	
	A4	5,859,205	01-12-1999	Adair <i>et al.</i>	
	A5	5,877,293	03-02-1999	Adair <i>et al.</i>	
	A6	5,929,212	07-27-1999	Jolliffe <i>et al.</i>	
	A7	5,945,098	08-31-1999	Sarno <i>et al.</i>	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	A8	EP 101 681 B1	03-07-1984	Rockefeller University		
	A9	EP 186 833 B2	07-09-1986	Yeda Research & Development		
	A10	EP 212 489 B1	03-04-1987	Rockefeller University		
	A11	EP 351 789 A2	01-24-1990	Chiron Corp.		
	A12	EP 366 043 A1	05-02-1990	Otsuka Pharmaceutical Co.		
	A13	WO 91/02078 A1	02-21-1991	Peptide Technology		
	A14	EP 492 448 A1	07-01-1992	Farmitalia Carlo Erba		
	A15	WO 92/11383 A1	07-09-1992	Celltech Ltd.		
	A16	WO 92/16553 A1	10-01-1992	New York University		
	A17	WO 93/06213 A1	04-01-1993	Medical Research Council		
	A18	WO 93/11793 A1	06-24-1993	Schering Corp.		

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NON PATENT LITERATURE DOCUMENTS			
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Examiner Signature		Date Considered	
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				Examiner Name	A.R. Chaudhuri
Sheet	2	of	4	Attorney Docket Number	BBI-190

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		Number-Kind Code ² (if known)			
	B1	5,994,510	11-30-1999	Adair <i>et al.</i>	
	B2	6,015,557	01-18-2000	Tobinick <i>et al.</i>	
	B3	6,024,938	02-15-2000	Corbo <i>et al.</i>	
	B4	6,090,382	07-18-2000	Salfeld <i>et al.</i>	
	B5	6,171,586 B1	01-09-2001	Lam <i>et al.</i>	
	B6	6,214,870 B1	04-10-2001	McClure <i>et al.</i>	
	B7	6,235,281 B1	05-22-2001	Stenzel <i>et al.</i>	
	B8	6,258,562 B1	06-10-2001	Salfeld <i>et al.</i>	
	B9	6,270,766 B1	08-07-2001	Feldman <i>et al.</i>	
	B10	6,423,321 B2	07-23-2002	Tobinick <i>et al.</i>	
	B11	6,509,015 B1	01-21-2003	Salfeld <i>et al.</i>	
	B12	6,537,549 B2	03-25-2003	Tobinick	
	B13	2003/0124119 A1	07-03-2003	Yamazaki, <i>et al.</i>	

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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	B14	EP 614 984 A2	09-14-1994	Miles Inc.		
	B15	GB 2 279 077	12-21-1994	Celltech Ltd.		
	B16	WO 94/29347 A1	12-22-1994	Therapeutic Antibodies Inc.		
	B17	EP 659 766 A1	06-28-1995	Schering-Plough		
	B18	WO 95/23813	09-08-1995	Merck & Co., Inc.		
	B19	WO 97/04801 A1	02-13-1997	Genentech, Inc.		
	B20	WO 97/29131 A1	08-14-1997	BASF AG		
	B21	WO 98/56418 A1	12-17-1998	Genentech, Inc.		
	B22	EP 1 174 148 A1	01-23-2002	Yamanouchi Pharma Co.		
	B23	WO 02/12502 A2	02-14-2002	Centocor, Inc.		
	B24	EP 1 254 666 A1	11-06-2002	Chugai Seiyaku Kabushiki		
	B25	WO 02/100330 A2	12-19-2002	Abbott Laboratories		
	B26	WO 2004/004633 A2	01-15-2004	Abbott Laboratories		
	B27	WO 2004/09776 A2	01-29-2004	Abbott Laboratories		
	B28	WO 2004/016286 A2	02-26-2004	Abbott Laboratories		
	B29	WO 2004/037205 A2	05-06-2004	Abbott Biotechnology Ltd.		

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	C1	Barbuto <i>et al.</i> Production of Neutralizing Antibodies to Tumor Necrosis Factor by Human Tumor-Infiltrating B Lymphocytes. Proc. Am. Assoc. Cancer Res. 1993. 34:487, Abstract 2904.	
	C2	Bendtzen <i>et al.</i> Auto-Antibodies to IL-1 β and TNF α in Normal Individuals and in Infectious and Immunoinflammatory Disorders. The Physiological and Pathological Effects of Cytokines. Wiley-Liss, Inc., 1990, pp. 447-452.	
	C3	Boyle <i>et al.</i> A novel monoclonal human IgM autoantibody which binds recombinant human and mouse tumor necrosis factor-alpha. Cell Immunol. 1993 Dec;152(2):556-68.	
	C4	Boyle <i>et al.</i> The B5 monoclonal human autoantibody binds to cell surface TNF alpha on human lymphoid cells and cell lines and appears to recognize a novel epitope. Cell Immunol. 1993 Dec;152(2):569-81.	
	C5	Chow <i>et al.</i> Effect of Monoclonal Antibody on Human Tumor Necrosis Factor (TNF MAb) on TNF α , IL-1 β , and IL-6 Levels in Patients with Sepsis Syndrome. Clinical Research. 1994. 42(2):299A.	
	C6	Cleland <i>et al.</i> A specific molar ratio of stabilizer to protein is required for storage stability of a lyophilized monoclonal antibody. J Pharm Sci. 2001 Mar;90(3):310-21.	
	C7	Cox <i>et al.</i> A directory of human germ-line V kappa segments reveals a strong bias in their usage. Eur J Immunol. 1994 Apr;24(4):827-36.	
	C8	Elliott <i>et al.</i> Treatment of rheumatoid arthritis with chimeric monoclonal antibodies to tumor necrosis factor alpha. Arthritis Rheum. 1993 Dec;36(12):1681-90.	
	C9	Fomsgaard <i>et al.</i> Auto-antibodies to tumour necrosis factor alpha in healthy humans and patients with inflammatory diseases and gram-negative bacterial infections. Scand J Immunol. 1989 Aug;30(2):219-23.	
	C10	Griffiths <i>et al.</i> Human anti-self antibodies with high specificity from phage display libraries. EMBO J. 1993 Feb;12(2):725-34.	
	C11	Hillgren <i>et al.</i> Protection mechanism of Tween 80 during freeze-thawing of a model protein, LDH. Int J Pharm. 2002 Apr 26;237(1-2):57-69.	
	C12	Huse <i>et al.</i> Generation of a large combinatorial library of the immunoglobulin repertoire in phage lambda. Science. 1989 Dec 8;246(4935):1275-81.	
	C13	Kempner <i>et al.</i> Preliminary Results of Early Clinical Trials with the Fully Human Anti-TNF α Monoclonal Antibody D2E7 Annual Rheumatoid Disease. 1999. 58(1):170-172.	
	C14	Lerner <i>et al.</i> Antibodies without immunization. Science. 1992 Nov 20;258(5086):1313-4.	
	C15	Leusch <i>et al.</i> Failure to demonstrate TNF alpha-specific autoantibodies in human sera by ELISA and western blot. J Immunol Methods. 1991 May 17;139(1):145-7.	
	C16	Lewis <i>et al.</i> J. Cell. Biochem. 1994. 18D:215.	
	C17	Marks <i>et al.</i> By-passing immunization. Human antibodies from V-gene libraries displayed on phage. J Mol Biol. 1991 Dec 5;222(3):581-97.	
	C18	Möller <i>et al.</i> Monoclonal antibodies to human tumor necrosis factor alpha: in vitro and in vivo application. Cytokine. 1990 May;2(3):162-9.	

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Sheet	4	of	4	Attorney Docket Number	BBI-190

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	D1	Tomlinson <i>et al.</i> The structural repertoire of the human V kappa domain. EMBO J. 1995 Sep 15;14(18):4628-38.	
	D2	Tomlinson <i>et al.</i> The repertoire of human germline VH sequences reveals about fifty groups of VH segments with different hypervariable loops. J Mol Biol. 1992 Oct 5;227(3):776-98.	
	D3	Tracey <i>et al.</i> Tumor necrosis factor: a pleiotropic cytokine and therapeutic target. Annu Rev Med. 1994;45:491-503.	
	D4	Winter <i>et al.</i> Humanized antibodies. Immunol Today. 1993 Jun;14(6):243-6.	

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